A randomised controlled trial investigating the effect of POSition IN LABour and effect on pudendal nerve physiology

Submission date	Recruitment status	Prospectively registered
15/01/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
03/05/2007	Completed	Results
Last Edited	Condition category	Individual participant data
10/10/2014	Pregnancy and Childbirth	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Colm O Herlihy

Contact details

UCD School of Medicine and Medical Science University College Dublin National Maternity Hospital Holles Street Dublin Ireland

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

POSINLAB

Study objectives

The hypothesis of the trial is that direct pressure on the pudendal nerve and or sacral plexus during the first stage of labour rather than traction on the pelvic floor during the second stage of labour is supported by previous observations of our research group. Firstly pudendal nerve latency has been consistently shown to be prolonged more on the left than on the right. Secondly caesarean delivery late in labour does not prevent changes in pudendal nerve terminal motor latency.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committe of the National Maternity Hospital, 12/09/2002.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pudendal nerve neuropathy

Interventions

It is proposed to randomise sixty primparous women in the first stage of labour to conventional nursing on the left side or nursing on alternate sides every 30 minutes. Delivery would be in the left lateral position in group one and in the lithotomy position in group two.

Pelvic floor Electromyography (EMG), anorectal manometry and continence scoring would be performed at the six week postnatal check.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The effects on pudendal nerve motor latency

Secondary outcome measures

The difference in anaorectal manometry and continence scoring between the groups

Overall study start date

01/02/2007

Completion date

30/06/2007

Eligibility

Key inclusion criteria

Primiparous healthy patients who are in labour with a single cephalic foetus

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

60

Key exclusion criteria

- 1. Patients with a history of bowel symptoms or bowel surgery
- 2. Patients without fluent English
- 3. Diabetic patients
- 4. Patients attending the hospital High Risk Clinic

Date of first enrolment

01/02/2007

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

Ireland

Study participating centre
UCD School of Medicine and Medical Science
Dublin

Ireland

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Sponsor information

Organisation

Health Research Board of Ireland (Ireland)

Sponsor details

73 Lower Baggot Street Dublin Ireland 2

Sponsor type

Government

Website

http://www.hrb.ie/

ROR

https://ror.org/003hb2249

Funder(s)

Funder type

Government

Funder Name

Health Research Board of Ireland (Ireland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration